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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,996	11/21/2003	Abdelali Hannoufa	1096.021A	3650

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EXAMINER
PAGE, BRENT T

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,996	HANNOUFA ET AL.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 25-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/21/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 03/08/2004*.

DETAILED ACTION

Applicant's election with traverse of Group IV in the reply filed on 4/20/2006 is acknowledged. The traversal is on the grounds that a search of the invention of Group IV would be sufficient for a search of the other Inventive Groups. This is not found persuasive because the invention of Group I, for instance specifies SEQ ID NO's that a search of Group IV would not be sufficient to search, Group II would require a search for SEQ ID NO:8 which a search of Group IV would not be sufficient for and Group III would require a search for specific named genes of interest that a search of Group IV would not be sufficient for.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The embedded hyperlink occurs in paragraph 97 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 24 is objected to because of the following informalities: Claim 24 in part ii recites "with a nucleic the molecule". This is interpreted to be a typographical error with missing words or awkward language. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 21 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 21 of copending Application No. 10995951. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 21 of this application conflicts with claim 21 of Application No. 10995951. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 19-20 and 22-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10995951. Although the conflicting claims

are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the use of ROS and other repressor genes for plant transformation, wherein tissue specific and development specific promoters are well known in the art and represent design choices that would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method for selectively controlling the transcription of a gene of interest comprising the transformation of a plant with a genetic construct wherein the construct may comprise a multitude of nucleic acid sequences which comprise a ROS operator, and a second transformation of a genetic construct comprising a multitude of ROS repressors.

In contrast the specification only provides guidance for the full length sequence of SEQ ID NO:2 as a functioning ROS repressor.

The ability of altered nucleic acids to function as ROS repressors is unpredictable. In a study of a ROS mutant, Archdeacon et al (2000 FEMS Microbiology Letters 187:175-178) disclosed that a single substitution of a C to a T resulted in a ROS repressor that no longer functions as a repressor, despite the fact that the mutation is distal to the zinc finger in ROS.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate all nucleic acid sequences described above for their ability to function as ROS repressors as broadly claimed.

Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for selectively controlling the transcription of a gene of interest comprising the transformation of a plant with a genetic construct wherein the construct may comprise a multitude of nucleic acid sequences which comprise a ROS operator, and a second transformation of a genetic construct comprising a multitude of ROS repressors.

In contrast the specification only provides guidance for the full length sequence of SEQ ID NO:2 as a functioning ROS repressor.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ulmasov et al (1997 The Plant Cell 9:1963-1971).

The claim is broadly drawn to a method for selectively controlling the transcription of a gene of interest comprising transforming a plant with a first construct with comprising any operator sequence capable of controlling the transcription of a gene of interest, transforming a second plant with a second construct comprising a nucleic acid encoding any repressor exhibiting both repressor operator binding activity and repressor activity and breeding the two plants to obtain progeny containing both first and second constructs.

Ulmasov et al teach a plant cotransfected with two constructs, the first construct comprising a reporter gene and DR5 AuxREs, the second construct comprising soybean Aux22 wherein the expression of the reporter gene was repressed by the operator binding and repressor activity of Aux22 (see page 1967 2nd 3rd and 4th paragraphs for example).

Ulmasov et al did not teach transforming separate plants and mating them to obtain progeny comprising both constructs, however, plant transformation methods are well known in the art, and cotransfecting a plant is merely a design choice for transformation.

Given the state of the art and the disclosure by Ulmasov et al, it would have been therefore obvious for one of ordinary skill in the art to use the constructs designed by Ulmasov et al and modify the method by transforming each into individual plants and breeding the two plants to obtain progeny comprising both constructs.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulmasov et al.

The claims are broadly drawn to a method for selectively controlling transcription of a gene of interest comprising transforming a plant either with two genetic constructs comprising a ROS operator sequence and a ROS repressor respectively, or introducing one construct into a plant and crossing it with another plant wherein the second construct has been introduced into the second plant, wherein the nucleic acid molecule or derivative thereof is defined in the specification on page 6 as "comprising one or more of the following properties: b hybridizing under stringent conditions with the nucleotide sequence of SEQ ID NO:2 or 3, comprising hybridizing for 16-20 hours at 65 C in 7% SDS, 1mM EDTA 40mM Na2HPO4, pH 7.2, followed by washing in 5% SDS, 1mM EDTA 40mM Na2HPO4, pH 7.2 for 30 min, followed by washing in 1% SDS, 1mM EDTA 40mM Na2HPO4, pH 7.2 for 30 min". The conditions recited are low stringency conditions, are interpreted to read on any similar DNA sequence exhibiting ROS repressor activity.

Ulmasov et al teach a plant cotransfected with two constructs, the first construct comprising a reporter gene and DR5 AuxREs, the second construct comprising soybean Aux22 wherein the expression of the reporter gene was repressed by the operator binding and repressor activity of Aux22 (see page 1967 2nd 3rd and 4th paragraphs for example).

Ulmasov et al did not teach breeding steps, nuclear localization signals, or inducible or tissue specific promoters. However, plant transformation methods including breeding steps, nuclear localization signals and inducible and tissue

specific promoters are well known in the art and represent design choices that would be obvious to one of ordinary skill in the art to apply to a plant system.

Given the state of the art and the disclosure by Ulmasov et al, it would have been therefore obvious for one of ordinary skill in the art to use the constructs designed by Ulmasov et al and modify the method by transforming each into individual plants and breeding the two plants to obtain progeny comprising both constructs, and add nuclear localization signal sequences and inducible or tissue specific promoters.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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GROUP ~~180~~ 1638